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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: K071081

1. Date of Submission: Nov 28, 2006

2. Applicant Device Information

Trade/Proprietary Name: Contact Lens Case (Multiple Brand Names)
Common Name: Contact Lens Case
Classification Name: Case, Contact Lens
Device Class: II
Product Code: LRX
Regulation Number: 886.5928
Intended Use:
The Applicant contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses while not being worn. Not designed for heat disinfecting system. Use only with chemical disinfection.

3. Submitter Information

Manufacturer Name:
Ningbo Kaida Rubber & Plastic Technology Co., Ltd.
No.1 Qinggang Industrial Park, Mou Shan Town,
Yu Yao City, Zhejiang Province,
China

Contact Person of the Submission:
Ms. Diana. Hong
Mr. Eric. Chen
Shanghai Mid-link Consulting Co., Ltd.
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4. Predicate Device

The Legally Marketed Contact Lens Case as predicate devices is identified as followings:

1) i-Promotions Contact Lens Case (K042578)
Manufactured by:
i-Promotions, Inc.
9522 Gravois Rd.
St. Louis, MO 63123

5. Device Description

The applicant device of Contact Lens Case is a device intended to be used by the contact lens wearer or practitioner for storing contact lenses while not being worn. The applicant device is not sterile and not for heat-disinfection.

Applicant Device Variants: SL-295, SL-298, SL-326, SL-338, SL-305, SL-316, SL-511, SL-800, SL-863, SL-884, SL-886, SL-869, SL-876, SL-880, SL-899

All the variant models as mention above follow the same design principle with the same intended use. The only difference is the dimension and appearance of each model, which do no effect on the usage and intended use and just for commercial purpose.

The applicant device of Contact Lens Case consists of 2 parts: case body and case cover. The case body is based with adjoining dual wells for the containment of fluid, and the cap is designed for screwing. All the variant models of the applicant device have a capacity of over 1.5 ml in each case well. And the inner height of the all well exceeds 8.5 mm. With regard to the Center Thickness of the normal hydrophilic and hydrophobic contact lens will not outnumber 8.5 mm, the capacity is sufficient for contact lens to be fully immersed under use condition.

The applicant device of Contact Lens Case made of 2 types of material of Polypropylene (PP) and Acrylonitrile – butadiene – styrene copolymer (ABS) for each variant model.

6. Substantially Equivalence Determination

Comparison Table of the Applicant Device and Predicate Device of Single Lumen

Comparison Elements	**Applicant Device**	**Predicated Device**
Device Name	Multiple Brand Names	2) i-Promotions Contact Lens Case (K042578)
Classification Name	Contact Lens Case	Contact Lens Case
Product Code	LRX	LRX
Comparison Statement	**The applicant device has same classification information as the predicate device.**	
Intended Use	The Applicant contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing contact lenses while not being worn. The applicant device is not designed for heat disinfecting system. Use only with chemical disinfection.	i-Promotions Contact Lens Case is intended for storage during disinfection of soft, rigid gas permeable or hard contact lenses. Not to be used with heat disinfection. Use only with chemical disinfection.
Indications	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard	Storage and Disinfection of Soft, Rigid Gas Permeable or Hard
Comparison Statement	**The applicant device has same indications and intended use as the predicate device.**	
Disinfection Type	Chemical Disinfection	Chemical Disinfection
	Not Heat-Disinfection	Not Heat-Disinfection
Design	Two adjoining Wells Screwed with Screw Top into Which	Two adjoining Wells Screwed with Integral Hinged Cap into Which Respective Lenses are Immersed
Main Material	SK Corporation Polypropylene (PP) R370Y with certificated quality	Dow Chemical Company Low Density Polyethene Dow Product #9931 See 510(k) (K993486)
	Acrylonitrile – butadiene – styrene copolymer (ABS) PA – 757K	
	Carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Color Index No. 51319)	
Comparison Statement	**The applicant device has similar product design as the predicate device. The only difference is the ABS material**	

	applied. But all the material including PP, ABS, and the colorant are demonstrated as safe in the biocompatibility reports data provided in Chapter IV, Biological Specifications and Appendix 1, Biocompatibility Reports. And the colorant Carbazole viole (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Color Index No. 51319) is exempt from the certification requirement of 721(c) of FD&C Act as to the requirements of 21 CFR 73.3107			
Effectivencss Elements	The capacity is sufficient for contact lens to be fully immersed under use condition.		Two adjoining Wells Screwed with Integral Hinged Cap into Which Respective Lenses are Immersed	
Comparison Statement	**The applicant device has same performance effectiveness as the predicate device.**			
Safety Elements	Polypropylene (PP) R370Y		Low Density Polyethene Dow Product #9931	
	In Vitro Cyto-toxicity	No Cyto-toxicity	*In Vitro* Cyto-toxicity	No Cyto-toxicity
	Delayed-type Hypersensitivity	No delayed dermal contact sensitization	Delayed-type Hypersensitivity	No delayed dermal contact sensitization
	Eye Irritation	No intracutaneous reactivity	Eye Irritation	No intracutaneous reactivity
	Systemic Toxicity	No systemic toxicity	Systemic Toxicity	No systemic toxicity
	Acrylonitrile – butadiene – styrene copolymer (ABS) PA – 757K			
	In Vitro Cyto-toxicity	No Cyto-toxicity		
	Delayed-type Hypersensitivity	No delayed dermal contact sensitization		
	Eye Irritation	No intracutaneous reactivity		
	Systemic Toxicity	No systemic toxicity		
	Polypropylene (PP) R370Y with colorant of Carbazole violet			
	In Vitro Cyto-toxicity	No Cyto-toxicity		
	Delayed-type Hypersensitivity	No delayed dermal contact sensitization		
	Eye Irritation	No intracutaneous reactivity		
	Systemic Toxicity	No systemic toxicity		
Comparison Statement	**The applicant device has same performance safety as the predicate device.**			

RESULT OF COMPARISON
The applicant device has same classification information, same indications and intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The only difference is the ABS material and colorant applied.

Conclusion:

The applicant device has same classification information, same indications and intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The only difference is the ABS material and colorant applied. But all the material including PP, ABS, and the colorant are demonstrated as safe in the biocompatibility reports data provided in Chapter IV, Biological Specifications and Appendix 1, Biocompatibility Reports. And the colorant Carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Color Index No. 51319) is exempt from the certification requirement of 721(c) of FD&C Act as to the requirements of 21 CFR 73.3107

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

7. Effectiveness and Safety Considerations

Effectiveness:

All the variant models of the applicant device have a capacity of over 1.5 ml in each case well. And the inner height of the all well exceeds 8.5 mm. With regard to the Center Thickness of the normal hydrophilic and hydrophobic contact lens will not outnumber 8.5 mm, the capacity is sufficient for contact lens to be fully immersed under use condition.

Safety Considerations:

The test results of biocompatibility of Polypropylene (PP) contact lens (SL-884 is sampled for the test) are presented as Table IV-5 for the consideration of Biological Specifications.

The test results of biocompatibility of Acrylonitrile – butadiene – styrene copolymer (ABS) contact lens case (SL-800 is sampled for the test) are presented as **Table IV-6** for the consideration of Biological Specifications

The test results of biocompatibility Polypropylene (PP) contact lens case with colorant Carbazole violet (Pigment Violet 23) (SL-295 is sampled for the test) are presented as **Table IV-7** for the consideration of Biological Specifications.

Per 21 CFR 73.3107, Carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Color Index No. 51319) is exempt from the certification requirement of 721(c) of FD&C Act.

Conclusion: The all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the possible skin-contact component material in the finished product meets the requirement of Biocompatibility

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ningbo Kaida Rubber and Plastic Technology Co., Lt
c/o Marc M. Mouser
Underwriters Laboratories, Inc.
Laboratory and Testing
2600 NW Lake Rd.
Camas, WA 98607

MAY - 1 2007

Re: K071081
Trade/Device Name: Contact Lens Case (Multiple Brand Names)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: March 1, 2007
Received: April 17, 2007

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~Pending~~ K071081

Device Name: Contact Lens Case

Indications for Use:

The Applicant contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses while not being worn. Not designed for heat disinfecting system. Use only with chemical disinfection.

Prescription Use ____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K071081

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